

REMARKS

The subject nutritional or dietary supplement composition as disclosed and claimed addresses a particular need to strengthen and promote retinal health through the prevention, stabilization, reversal and/or treatment of visual acuity loss in people with particular ocular diseases.

Support for the amendments to claims 14 and 21 above is found for example on page 8, line 1 and page 9, lines 3-8 in addition to other locations throughout the subject specification.

Claim 21 stands rejected under 35 U.S. C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

Applicants respectfully traverse the rejection of claim 21 under 35 U.S.C. 112, first paragraph. Based on the above amendment to claim 21, in accordance with comments by the Examiner, the rejection of claim 21 under 35 U.S.C. 112, first paragraph, is now inappropriate. Withdrawal of the rejection of claim 21 under 35 U.S.C. 112, first paragraph, is respectfully requested.

Claim 14 stands rejected under 35 U.S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants respectfully traverse the rejection of claim 14 under 35 U.S.C. 112, second paragraph. Based on the above amendment to claim 14, in accordance with comments by the Examiner, the rejection of claim 14 under 35 U.S.C. 112, second paragraph, is now inappropriate. Withdrawal of the rejection of claim 14 under 35 U.S.C. 112, second paragraph, is respectfully requested.

Claims 1-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek, U.S. Patent Number 6,103,756, alone or in view of Newsome, D.

A., et al., Oral Zinc in Macular Degeneration, Arch. Ophthalmol., Vol. 106, February 1988, pp. 192-198.

Applicants respectfully traverse the subject rejection of claims 1-25 under 35 U.S.C. 103(a). Gorsek, '756 teaches a formulation for treating macular degeneration comprising as **essential ingredients** vitamin C, vitamin E, vitamin A, magnesium, L-taurine, selenium, bilberry extract, a natural fruit with standardized anthocyanosides, lutein extract, lycopene, alpha lipoic acid, quercetin, rutin and citrus bioflavonoids, in addition to other non-essential ingredients.

D. A. Newsome, in the cited publication teaches the administration of 5.3 times the RDA of zinc to treat macular degeneration in humans.

The subject invention as disclosed and claimed is directed to an unique dietary supplement formulation proven in a ten year study to promote retinal health through the prevention, stabilization, reversal and/or treatment of visual acuity loss in people with particular ocular diseases. The subject formulation which differs significantly from the teachings of both Gorsek, '756 and D.A.

Newsome et al., comprises **6 to 10 times the RDA of vitamin A, 7 to 10 times the RDA of vitamin C, 13 to 18 times the RDA of vitamin E, 4 to 7 times the RDA of zinc and approximately the RDA of copper. Gorsek, '756 teaches away from the subject claimed formulation.** Gorsek, '756 teaches a formulation comprising among other essential ingredients, **3.5 times the %DV of vitamin A, 16.7 times the %DV of vitamin C, 17 times the %DV of vitamin E, and among other non-essential ingredients, 1.6 times the %DV of zinc and 0.5 times the %DV of copper.** Accordingly, the subject formulation as compared to the Gorsek, '756 formulation comprises approximately a **2 to 3 times greater amount** of vitamin A, approximately **half** the amount of vitamin C, approximately within the **same** range of vitamin E, approximately 2 to 3 times **greater** amount of zinc

and approximately **double** the amount of copper. Gorsek, '756 teaches away from the importance of the subject five ingredients and the essential formulation amounts disclosed and claimed in the subject application. The subject unique formulation as described and claimed is not made obvious in light of the teachings of Gorsek, '756. Likewise, the subject formulation is not obvious in light of the cited D.A. Newsome et al., publication. D. A. Newsome et al., teach the administration of **solely** 5.3 times the RDA of zinc for macular degeneration. As further taught by D. A. Newsome et al., "[t]wo subgroups, namely, women and persons with a disciform scar or central atrophy in one eye, showed a positive trend but not a statistically significant effect" and "[t]here were . . . some persons in the zinc-treated group with visual loss as profound as some in the placebo group". According to such teachings, the use of zinc alone does not appear to be as beneficial as one may like. If one were to combine the teachings of Gorsek, '756 and D.A. Newsome et al, although not suggested by either reference, one would have the essential ingredients of Gorsek, '756 plus 5.3 times the RDA of zinc as taught by D. A. Newsome et al., from which the subject formulation differs significantly as pointed out above. Accordingly, the unique formulation of the present invention as disclosed and claimed in the subject application differs significantly from the teachings of Gorsek, '756 and D.A. Newsome et al, whether considered individually or in combination. For these reasons in addition to others not set forth herein, the rejection of claims 1-25 under 35 U.S.C. 103(a) is thereby inappropriate. Withdrawal of the rejection claims 1-25 under 35 U.S.C. 103(a) is respectfully requested.

Claims 1-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LaHaye et al., U.S. Patent Number 5,075,116 in view of Gorsek, '756 further in view of Newsome.

Applicants respectfully traverse the subject rejection of claims 1-25 under 35 U.S.C. 103(a). LaHaye et al., '116 teach a formulation for treating macular degeneration with vitamins C and E, zinc, copper, selenium, manganese and at least one of L-cysteine, pyridoxine and riboflavin.

Gorsek, '756 teaches a formulation for treating macular degeneration comprising as **essential ingredients** vitamin C, vitamin E, vitamin A, magnesium, L-taurine, selenium, bilberry extract, a natural fruit with standardized anthocyanosides, lutein extract, lycopene, alpha lipolic acid, quercetin, rutin and citrus bioflavonoids, in addition to other non-essential ingredients.

D. A. Newsome, in the cited publication teaches the administration of 5.3 times the RDA of zinc to treat macular degeneration in humans.

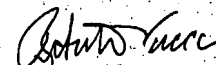
The subject invention as disclosed and claimed is directed to a unique dietary supplement formulation proven in a ten year study to promote retinal health through the prevention, stabilization, reversal and/or treatment of visual acuity loss in people with particular ocular diseases. The subject formulation which differs significantly from the teachings of LaHaye et al., '116, Gorsek, '756 and D.A. Newsome et al., comprises **6 to 10 times the RDA of vitamin A, 7 to 10 times the RDA of vitamin C, 13 to 18 times the RDA of vitamin E, 4 to 7 times the RDA of zinc and approximately the RDA of copper. LaHaye et al., '116 teaches away from the subject claimed formulation. LaHaye et al., '116 teaches a formulation comprising among other essential ingredients 33.3 times the RDA of vitamin C, 2 times the RDA of vitamin E, 6.7 times the RDA of zinc and 2 times the RDA of copper with no teaching with regard to vitamin A. Accordingly, the subject invention as compared to the LaHaye et al., '116 formulation comprises approximately 3 to 5 times less vitamin C, approximately 6 to 9 times more vitamin E, approximately within the same range of zinc and approximately half the amount of copper. LaHaye et al., '116 teach away from**

the importance of the subject five ingredients and the essential formulation amounts disclosed and claimed in the subject application. The subject unique formulation as described and claimed is not made obvious in light of the teachings of LaHaye et al., '116. Likewise, the subject formulation is not obvious in light of Gorsek, '756 and D.A. Newsome et al., for the reasons set forth above. If one were to combine the teachings of LaHaye et al., '116, Gorsek, '756 and D.A. Newsome et al., although not suggested by any of the references, one would have the essential ingredients of Gorsek, '756 or the differing essential ingredients of LaHaye et al., '116, plus 5.3 times the RDA of zinc as taught by D. A. Newsome et al. The unique formulation of the present invention as disclosed and claimed in the subject application differs significantly from the teachings of LaHaye et al., '116, Gorsek, '756 and D.A. Newsome et al. whether considered individually or in combination. For these reasons in addition to others not set forth herein, the rejection of claims 1-25 under 35 U.S.C. 103(a) is thereby inappropriate. Withdrawal of the rejection claims 1-25 under 35 U.S.C. 103(a) is respectfully requested.

Pending claims 1-25 as now amended are believed to be patentable. Allowance of pending claims 1-25 is thereby respectfully requested.

Should there be any questions regarding this communication, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

 10/7/02

Rita D. Vacca
Reg. No.: 33,624

Bausch & Lomb, Inc.
One Bausch & Lomb Place
Rochester, New York 14604-2701